

SUPPORT FOR AMENDMENT

In response to the non-final Office Action, dated October 25, 2002, the applicant hereby makes the following response. Claims 1-20 are currently pending with claims 1, 10, 11 and 15 being independent. In this response, claims 1, 7, 10, 11, 12, 13 and 15 are being amended while claims 8 and 9 are being cancelled.

The amendment to claims 1, 10, 11 and 15 is supported by claim 9, and the specification, page 6, lines 23-30. Claims 7, 12 and 13 have been clarified. No new matter has been added.

A marked up version of the amended claims has been included as an appendix. Upon entry of this amendment, claims 1-7 and 10-20 are present and active in the application.

REQUEST FOR RECONSIDERATION

The present invention relates to hypodermic needles for collecting blood samples for laboratory testing. Conventional hypodermic needles typically include a hollow shaft having a cylindrical inner surface, a cylindrical outer surface and a piercing part that is a more or less sharply angled wedge at one end of the needle. A problem often encountered with conventional needles is hemolysis. Hemolysis occurs when the membrane surrounding red blood cells is ruptured and hemoglobin and other intracellular components escape into the serum or plasma. The present invention avoids this problem.

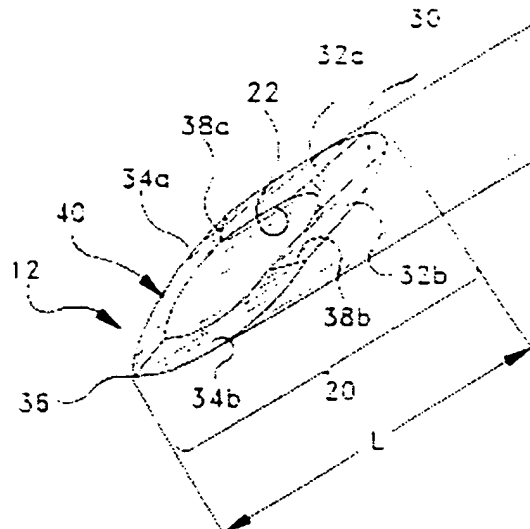
The present invention includes an internal substantially cylindrical surface, an external substantially cylindrical surface, and an end formed at an angle with respect to the longitudinal

axis of the needle. The needle has an oval opening inline with the bore of the needle. An exterior planar rim having an external edge and an internal edge partially or wholly extends around the circumference of the opening. At least a portion of the rim is beveled inwardly toward the interior of the needle to form a beveled surface that faces the interior of the needle and extends partially around the inner circumference of the entrance of the needle opening. Thus, the present invention provides an opening that facilitates uniform fluid flow and reduces fluid stresses at the entrance of the needle and minimizes hemolysis during blood collection.

The rejection of claims 1-5, 11-13 and 15-20 under 35 U.S.C. 112, second paragraph is respectfully traversed. Claims 1, 11 and 15 have been amended to further define the invention indicating the external peripheral rim bevels with respect to the wall thickness of the tube (see specification page 7, lines 14-22).

The rejection of claims 1-20 under 35 U.S.C. 102(b) over *Doyle* is respectfully traversed. As now claimed, the present invention specifies that the peripheral rim is beveled back at least 25% with respect to the wall thickness of the tube. Additionally, as now claimed, the present invention specifies that the internal beveled surface surrounds 20-70% of the opening.

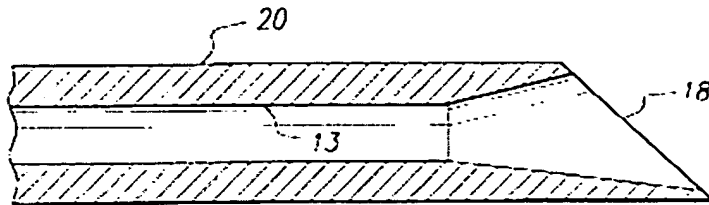
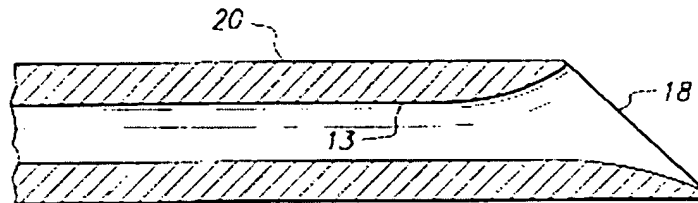
In contrast, *Doyle* specifically discloses that the beveled surface completely surrounds the opening as shown in the partial portion of Fig. 1 shown below.



Accordingly, the applicant respectfully submits that *Doyle* does not anticipate the claimed present invention. Withdrawal of this ground of rejection is respectfully traversed.

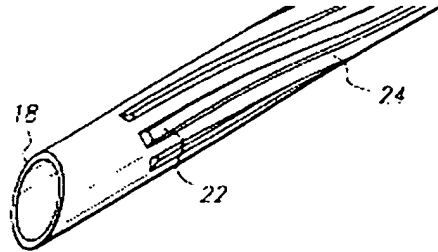
The rejection of claims 1-6, 8, 10-18 and 20 under 35 U.S.C. 102(b) over *Barrett* is respectfully traversed. As now claimed, the present invention specifies that the peripheral rim is beveled back at least 25% with respect to the wall thickness of the tube. Additionally, as now claimed, the present invention specifies that the internal beveled surface surrounds 20-70% of the opening.

Barrett relates to a phaco-emulsification needle having grooves to supply aspirating fluid. *Barrett* discloses a funnel shaped and a curved horn shaped tip (see column 5, lines 55-60 and Figures 7A and 7B). As shown in Figures 7A and 7B, the reference does not teach an internal beveled surface that bevels at least 25% with respect to the wall thickness of the tube. In Figure 7A, the opening slants with respect to the tube while in Figure 7B the opening slightly curves with respect to the tube.

**FIG. 7A****FIG. 7B**

With respect to Figure 7B, as noted in M.P.E.P. § 2125, when the specification “does not disclose that the drawings are to scale and is silent as to dimensions, arguments based on measurement of the drawing features are of little value.” Manual Of Patent Examining Procedure, § 2125 (8th ed. August 2001).

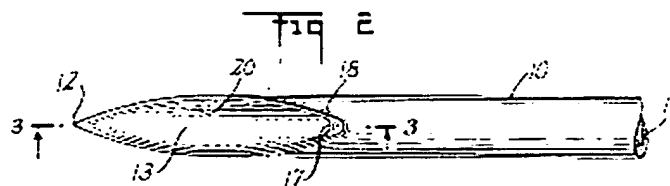
Furthermore, as now claimed, the present invention specifies that the internal beveled surface surrounds 20-70% of the opening. In contrast, *Barrett* does not describe specifies that the internal beveled surface surrounds 20-70% of the opening. *Barrett* specifically discloses that the beveled surface completely surrounds the opening as shown in the partial portion of Fig. 5 shown below.



Accordingly the applicant respectfully submits that *Barrett* does not anticipate the claimed present invention. Withdrawal of this rejection is respectfully traversed.

The rejection of claims 1-20 under 35 U.S.C. 102(b) over *Henderson* is respectfully traversed. As now claimed, the present invention specifies that the peripheral rim is beveled back at least 25% with respect to the wall thickness of the tube. Additionally, as now claimed, the present invention specifies that the internal beveled surface surrounds 20-70% of the opening.

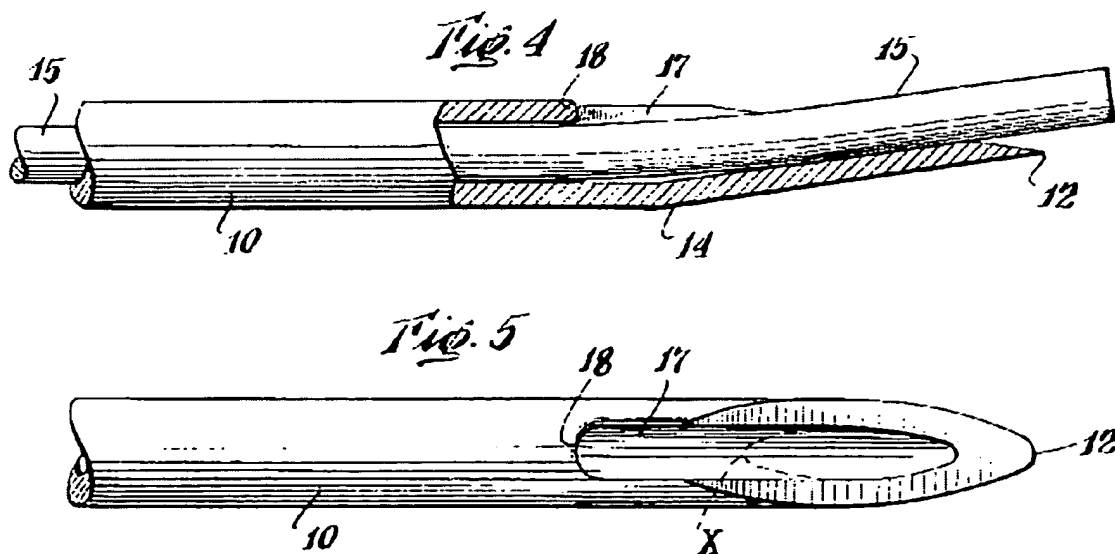
In contrast, *Henderson* specifically discloses that the beveled surface surrounds less than 20% of the opening as shown in element 17 in the partial portion of Fig. 2 shown below.



Accordingly, the applicant respectfully submits that *Henderson* does not teach the present invention. Withdrawal of this ground of rejection is respectfully traversed.

The rejection of claims 1-20 under 35 U.S.C. 102(b) over *Huber* is respectfully traversed. As now claimed, the present invention specifies that the peripheral rim is beveled back at least 25% with respect to the wall thickness of the tube. Additionally, as now claimed, the present invention specifies that the internal beveled surface surrounds 20-70% of the opening.

In contrast, *Huber* specifically discloses a portion of the needle being bent relative to the axial line of the cannula to prevent tissue plug cutting. To prevent tissue cutting, *Huber* further discloses that the recess (element 16 in Fig. 3) is cut away depending on the angle which the needle is bent (see column 3, lines 15-21). As shown in Figures 4 and 5, reproduced below, only a small portion of the rim is rounded off. *Huber* does not bevel back the internal surface which surrounds 20-70% of the opening.



Accordingly, the applicant respectfully submits that *Huber* does not teach the present invention. Withdrawal of this ground of rejection is respectfully traversed.

Applicant submits that the application is now in condition for allowance. Early notice of such action is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Paul E. Rauch', with a long horizontal line extending to the right.

Paul E. Rauch, Ph.D.
Reg. No. 38,591

SONNENSCHN NATH & ROSENTHAL
P.O. Box #061080
Wacker Drive Station
Sears Tower
Chicago, Illinois 60606-1080

Direct telephone calls to: (312) 876-7440

APPENDIX

Marked Up Version of Amended Claims and Specification

1. (Once Amended) A hypodermic needle, comprising:
a hollow tube having an angled end with respect to a longitudinal axis of the tube, the end having an opening surrounded by an external peripheral rim,

wherein at least a portion of the external peripheral rim is beveled back at least 25%[,] with respect to a wall thickness of the tube to form an internal beveled surface such that the internal beveled surface surrounds 20-70% of the opening.

7. (Once Amended) The hypodermic needle of claim [1] 6 wherein a circle coincident with the curvature of the internal beveled surface has a radius of curvature that is at least 25% [of thickness of a wall of the needle] with respect to the wall thickness.

10. (Once Amended) A hypodermic needle, comprising:
a hollow tube having an angled end with respects to a longitudinal axis of the tube, the end having a means for reducing fluid stress at an entrance of the needle. the means for reducing fluid stress comprising an opening surrounded by an external peripheral rim wherein at least a portion of the external peripheral rim is beveled back at least 25% with respect to a wall thickness of the tube to form an internal beveled surface such that the internal beveled surface surrounds 20-70% of the opening[, and

means for reducing fluid stress at the entrance of the needle].

11. (Once Amended) In a hypodermic needle having an internal substantially cylindrical surface; an external substantially cylindrical surface; an end angled with respect to a longitudinal axis of the needle, the end having an opening and defining a piercing tip; an outer peripheral rim, the rim partially surrounding a first region of the opening proximal to the piercing

tip and connecting the external and internal cylindrical surfaces of the needle; the improvement, comprising:

an internal beveled surface on the internal surface of the needle [partially] surrounding 20-70% of a second region of said opening opposite the first region, wherein the degree of beveling back of the rim is at least 25% with respect to a wall thickness of the hypodermic needle.

12. (Once Amended) The hypodermic needle of claim 11, wherein [the] at least a portion of the external peripheral rim is beveled back at least 30%

13. (Once Amended) The hypodermic needle of claim 11, wherein [the] at least a portion of the external peripheral rim is beveled back at least 50%.

15. (Once Amended) In a method of preparing a sample, comprising:
withdrawing blood with a hypodermic needle, the hypodermic needle having an internal substantially cylindrical surface; an external substantially cylindrical surface; an end angled with respect to a longitudinal axis of the needle, the end having an opening and defining a piercing tip; an outer peripheral rim, the rim partially surrounding a first region of the opening proximal to the piercing tip and connecting the external and internal cylindrical surfaces of the needle; the improvement comprising withdrawing [the] blood with [a] the hypodermic needle having an internal beveled surface on the internal surface of the hypodermic needle [partially] surrounding 20-70% of a second region of said opening opposite the first region, wherein the degree of beveling back of the rim is at least 25% with respect to a wall thickness of the hypodermic.

Please replace the second, third, fourth and fifth paragraphs on page 6 with the following substituted paragraphs.

-- As shown in Figure 5, a generally planar external peripheral rim 44 having an outer edge 46 and an inner edge 48, front half and rear half regions 50 and 52, respectively, surrounds the opening 40 and connects the internal and external cylindrical surfaces 32 and 34 of the needle 30.

In conventional needles, shown in Figures 2 and 3, the external peripheral rim 22 surrounds the entire circumference of the opening 18. Due to the angling of the end 28, the inner edge [24] 26 of the rim 22 presents a cutting edge around the entrance of the needle 10. As is most clearly shown in Figure 3, the inner cutting edge [24] 26 is particularly pronounced at the entrance in the rear region 27 of the end 28 of the needle 10.

Our studies and modeling have shown that in conventional needles such as those shown in Figures 1, 2, and 3, the inner edge [24] 26 of the rim 22 causes or contributes to an increase of non-uniform fluid flow and significant gradients in normal and shear stresses at the entrance to the needle opening. Figure 15 partially illustrates the non-uniform flow of fluid at the entrance of the opening of a conventional needle around [internal] the inner edge [24] 26.

In the present invention, as shown in Figures 4 and 5, the rim 44 and the inner edge 48 which form a cutting edge in conventional needles, is beveled back to form an internal beveled surfaced 58 that at least partially surrounds the inner periphery of the opening 40. The internal beveled surface 58 is usually located in the rear half region 52, and may extend into the front half region 50. The internal beveled surface 58 surrounds preferably five percent to eighty-five percent of the inner periphery of the opening 40, more preferably from twenty percent to seventy percent of the inner periphery of the opening 40, and most preferably from thirty percent to seventy percent of the inner periphery of the opening 40. --

Please replace the last and second to last paragraphs on page 7 with the following substituted paragraphs.

-- The internal beveled surface 58 may present a straight surface [60] 70 as shown in Figure 12 and 13, or a convex surface curved by varying degrees toward the interior of the needle, 30 as shown in Figures 6, 8, 9, 16 and 18. The degree of beveling back is preferably at least 25% of the thickness of the wall 70 of the needle 30, and may be 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95 or 100%. The degree of beveling back is the distance 84, as a percentage of the wall thickness, between the original external surface 80 and the original internal surface 82 at the farthest point of the beveled surface 58, as shown in Figures 6 and 12.

When the internal beveled surface 58 is curved, as may be obtained with a round-over milling cutter, a circle coincident with the curvature of the beveled portion has a radius of curvature that is preferably at least 25% of the thickness of the wall 70 of the needle, 30 and may be 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95 or 100% of the thickness of the wall of the needle. Preferably, a circle coincident with the curvature of the beveled portion has a radius of curvature that is from 30% to 100%, more preferably from 50% to 100%, and most preferably from 75% to 100% of the thickness of the wall 70 of the needle. --

Please replace the first paragraph on page 8 with the following substituted paragraph.

-- When the internal beveled surface 58 is curved, the entrance of the needle has a partial bell-mouth configuration. In this configuration, as well as when the internal beveled surface is not curved, the interior space of the needle 30 in the region of beveling is frustoconical as shown by the dotted lines 90 in Figure 20. --